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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,393	03/22/2001	David N. Krag	34114-8001US1	5450

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/815,393

**Applicant(s)**

Krag, David N.

**Examiner**

Jessica R Baxter

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-36, 65-68, 70-76, 78-88 and 90-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 93-97 and 99 is/are allowed.
- 6) ☒ Claim(s) 32-36, 65-68, 74-76, 78-85, 87, 88, 92 and 98 is/are rejected.
- 7) ☒ Claim(s) 70-73, 86, 90 and 91 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Specification*

1. An objection was made to the specification. Correction is noted and the objection is withdrawn.

### *Drawings*

2. The objections to the drawings are withdrawn.

### *Claim Rejections - 35 USC § 112*

3. Claims 34, 79, 94, and 95 were rejected under 35 U.S.C. 112, second paragraph. Correction is noted and the rejections are withdrawn.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 32, 35, 36, 65, 66, 68, 74-76, 78-85, 87, 88, 92 and 98 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,707,362 to Yoon.

Regarding claims 32, 35, 36, 65, 66, 68, 74, 75, 78, 80-83, 92 and 98, Yoon discloses a tissue anchor comprising an elongate tube (30) having a closed distal end adapted to be advanced into the tissue mass (86), a central bore, and a plurality of apertures (40) extending through the wall; a manually controllable actuator (24) carried by an elongate tube and comprising an elongate member

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(32) sized for a close sliding fit within the central bore of the elongate tube, the actuator being movable with respect to the elongate tube between a first position and a second position; and a plurality of manually deployable anchor members (44), with one anchor member being associated with an aperture of the elongate tube (FIGS 2 and 3), each of the anchor members being operatively connected to the actuator such that each anchor member assumes a retracted position when the actuator is in its first position (FIG. 6) and each anchor assumes an extended position when the actuator is in its second position (FIG. 7 and Column 10 lines 25-43), each anchor member in its retracted position having a major portion received within the central bore of the elongate tube (FIG. 6), each anchor member in its extended position projecting outwardly from its associated aperture and assuming a curved configuration (FIG. 7).

Regarding claims 76 and 84, Yoon discloses that the apertures of the elongate tube are spaced proximally of the distal end (FIG. 2 slots 40).

Regarding claims 79 and 85, Yoon discloses a stop, the stop cooperating with the elongate tube (Column 8 lines 44-55).

Regarding claim 87, Yoon discloses that a small portion of each anchor member projects from its associated aperture when the rod is in its first position (see FIG. 6).

Regarding claim 88, Yoon discloses a method comprising the steps of advancing the distal end of the elongate tube into the tissue mass (FIG. 6 point 66), advancing the rod distally to its second position (FIG. 7), and drawing the tissue anchor proximally (Column 13 lines 3-9).

6. Claims 32, 35, 36, 65, 66, 67, 74 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,936,823 to Colvin et al.

Regarding claim 32, Colvin discloses a device comprising an elongate tube (see FIG. 1 body member 12) having a central bore (see FIG. 1A bore 22) a closed distal end (FIG. 2)

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and an aperture adjacent the distal end (see FIG. 1 slot 16), an elongate member (see FIG. 2 stem 20) with at least one anchor member attached (see FIG. 1 arm members 18), and the anchor member projects through the aperture and extends transversely (see FIG. 2 arm members 18 and slot 16).

Regarding claim 35, Colvin discloses that the at least one anchor member includes four anchor members (see FIG. 1 arm members 18).

Regarding claim 36, Colvin discloses that at least one anchor member has a curved configuration (see FIG. 2 arm members 18).

Regarding claim 65, Colvin discloses that the at least one aperture includes four apertures (see FIG. 1 slot 16).

Regarding claim 66, Colvin discloses that each anchor member projects from its associated aperture when the elongate member is in its first position (see FIG. 2).

Regarding claim 67, Colvin discloses that at least one anchor member includes a barb adjacent its distal end (see FIG. 1 arm members 18).

Regarding claim 74, Colvin discloses that a portion of the elongate member is sized for a close sliding fit with the central bore of the elongate tube (see FIG. 3).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon '362. Yoon discloses the claimed invention except for the size. It would have been an obvious matter of design choice to change the size, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

*Allowable Subject Matter*

9. Claims 70-73, 86, 90 and 91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 93-97 and 99 are allowed.


*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

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jrb

December 15, 2002